Message

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]
Sent: 12/17/2013 10:28:28 PM
To: Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Salazar, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd610df1d0c4db0b97eb0e00231461e-Salazar, Keith]
CC: Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]
Subject: RE: Inside EPA on ETBE and TBA and a question

Deliberative Process / Ex. 5 - Vince

-----Original Message-----
From: Deener, Kathleen
Sent: Tuesday, December 17, 2013 5:21 PM
To: Salazar, Keith
Cc: Birchfield, Norman; Cogliano, Vincent
Subject: RE: Inside EPA on ETBE and TBA and a question

Hi Keith -- thanks for sending this my way. I'm copying Norm and Vince so they can see the email from Kathy Burns (Norm has been working to gather some data about ETBE's occurrence) Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

As an aside, I think there may be a word missing from the last sentence. I think there should have been an "if" so the sentence reads "But if it is not in use..."

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-----Original Message-----
From: Salazar, Keith
Sent: Tuesday, December 17, 2013 5:09 PM
To: Deener, Kathleen
Subject: FW: Inside EPA on ETBE and TBA and a question

Hi Kacee,

Is this something I should respond to or should you?

Thanks.

Keith

-----Original Message-----
From: Kathy Burns [mailto:kmb@sciencecorps.org]
Sent: Tuesday, December 17, 2013 4:03 PM
To: Salazar, Keith
Subject: Inside EPA on ETBE and TBA and a question

Dear Dr. Salazar,

I just read the text towards the end of the article below. It deals with ETBE in the US. I am somewhat puzzled by the text because ETBE has been found in the drinking water aquifers in areas where gasoline spills occurred in the US. I have seen the analytical lab results myself. The same is true of TBA. Is it possible that there is some misunderstanding about when ETBE was used, where it was used, and the physicochemical conditions under which ETBE and TBA might be found in conjunction with MTBE or other additives in drinking water supplies?

Any light you can shed on this would be appreciated.

Regards,
Dr. Kathleen Burns

-----Original Message-----
Sent: Tuesday, December 17, 2013 2:03 PM
Subject: EPA Seeks To Improve IRIS Program's Output In 2014 - Oldeno

InsideEPA.com Tuesday, December 17, 2013
EPA Seeks To Improve IRIS Program's Output In 2014 But Faces Challenges

The leaders of EPA's Integrated Risk Information System (IRIS) are looking to continue to strengthen the influential toxicity hazard assessment program in 2014, including trebling the program's output within the next two or three years and publicly identifying the environmental and health concerns driving the need for the assessments.

But Vincent Cogliano, IRIS' acting director, told the Society for Risk Analysis annual meeting in Baltimore Dec. 10 that achieving those goals could prove to be ambitious, though he did not elaborate. "We have some challenges for next year," he said. "We have to increase productivity."

In one indication of the difficulties the program faces, agency officials appear to be considering dropping their long-running assessment of the fuel additive ethyl tert-butyl ether (ETBE). The assessment has been underway since 2004, according to EPA's IRIS Track website.

Questions about the uses of the chemical in the United States during the first of the IRIS program's bimonthly public meetings Dec. 12-13 in Arlington, VA, led the program's chief to announce he would determine why the chemical is under assessment.

Cogliano and other top officials have sought over the past year to prioritize and reduce the number of ongoing assessments that staff is handling in order to increase the program's efficiency and output, and meet goals for completing the reviews.

For example, Ken Olden, director of EPA's National Center for Environmental Assessment, who oversees the program, said last year the he intended to reduce the number of assessments underway from the existing 50 to 60 assessments to closer to 20.

Over the past year, he sought internal review of all assessments, including asking EPA program office staff why the assessment was nominated and whether it is still needed. Many assessments were delayed or removed from the schedule in order to hasten those considered most important (Risk Policy Report, Dec. 11, 2012).

But so far in 2013, the program has published only three final assessments
-- of biphenyl, 1,4-dioxane and of methanol's noncancer risks, as well as two draft assessments of benzo(a)pyrene and ethylene oxide.

"It's very important to us and our agency that we have a more productive IRIS program." Cogliano said, adding that increasing the program's output is "the number one job on my plate in this coming year."

He said that since 1996, the program has completed on average 4-5 assessments in a year. But when considering "the universe of chemicals in commerce, or the small universe of chemicals that EPA has on its regulatory lists, four to five assessments a year is just not acceptable. We expect to triple productivity within the next two to three years."

Cogliano said other priorities for IRIS staff include implementing a problem formulation for IRIS assessments, which will identify potential environmental or health problems driving the need for assessments, as well as internal changes in the documents' drafting.

"We're going to implement problem formulation. That's the next job . . .
that's going to be coming in the public meetings in 2014, in the assessments that we begin in 2014."

Cogliano noted that "internally we're implementing a new work flow that will better achieve IRIS objectives of improving science and increasing productivity." Cogliano declined to provide further detail on the new work flow, calling the changes "all internal."

After Cogliano's remarks, Elaine Faustman, a toxicology professor at the University of Washington, called "the development of problem formulation challenging," suggesting that very specific hypotheses, such as those used in mode of action (MOA), or the biological process of how a chemical causes a health effect, can be overwhelming when multiple MOAs are needed in an assessment.

Cogliano did not respond to her comment, but Deborah Cory-Slechta, a professor with the University of Rochester's medical school and a member of EPA's Science Advisory Board panel that will peer review the IRIS assessments, said that Faustman's "point is well-taken . . . in the case of something like the nervous system, if we had to figure out the MOA of loss of IQ, we'd never get anywhere . . ."

This issue of problem formulation came up repeatedly during the December bimonthly IRIS meeting, with Nancy Beck of the American Chemistry Council asking EPA for the background of each of the five chemicals under assessment, why they were nominated for assessment, what concerns the agency may have about a particular chemical, and what exposure pathways or features of the chemical are at issue.

Asked why chemicals' background is of interest, Beck told IRIS staff that she does not know why some chemicals are being assessed. "Are you concerned about dermal risk, oral risk, inhalation risks? I have no idea when I look at those evidence tables. . . . Which is the population of concern? . . . If you're really concerned about occupational exposures as your primary audience, there may be a whole different database that may be available . .
. You guys have limited time and there are a lot of chemicals. So for some reason these two or three chemicals are a big priority. And sometimes that's not clear to the public why it's a priority."

Olden responded that including such information, "should be done, and we're gonna do it, and we understand why we need to do it."

The long-running EPA assessment of ETBE provides a case study of the difficulty the agency faces in completing its analyses and the need for problem formulation.

A draft of the ETBE assessment was first released in 2009. But that document was caught up in concerns over IRIS' use of data from a controversial Italian laboratory, leading to delay and review of six IRIS assessments, both in progress and completed, that referenced Ramazzini Institute studies.
The agency announced last year that it would not use Ramazzini lymphoma or leukemia cancer data, and would only use the lab's hard tumor data in future. That included use of lymphoma or leukemia data in the assessment of ETBE, suggesting a re-write would be necessary (Risk Policy Report, March 13, 2012).

At the Dec. 12 bimonthly meeting, industry stakeholders asked why the agency was still conducting the assessment given that the substance is not likely to be used as a fuel additive.

ETBE is a fuel oxygenator widely used in Asia and Europe, but has never been used in the U.S., despite expectations a decade ago that it would also be used domestically.

"ETBE . . . is still registered at the federal level [for use in gasoline] but at least 14 or maybe its 19 . . . states have banned [it] for use in their state; makes it very difficult to put it in gasoline," Russell White, a toxicologist with the American Petroleum Institute, told IRIS staff in his prepared remarks.

He acknowledged, however, that some API member companies still manufacture the substance for sale in Asia and in Europe.

White, like other speakers, faulted agency staff for failing to conduct problem formulation of the IRIS assessments, which White and others suggested led to long IRIS reviews of chemicals that may not be particularly relevant to EPA or for regulatory purposes.

"Problem formulation was skipped over in this case," White said of the assessments of ETBE and its metabolite, tert-butanol (TBA). "EPA should consider the current status of these substances as fuel additives when they're trying to scope and formulating the problems."

White added that there is a long list of pending IRIS assessments awaiting publication and wondered why ETBE and TBA are still on the list. "There's a long list of IRIS chemicals to come. Should these be at the top of the list?" he said.

Olden asked "aren't there other uses of [ETBE] other than in fuel additives?"

White replied that he didn't know of any other uses. Fukumi Nishimaki, with the Japan Petroleum Energy Center, replied that ETBE is used in biofuels.

"Only in biofuels? I gather that's why it was nominated here?" Olden asked IRIS staff. "The intent was to add it to fuel and it was never done?"

Cogliano told Olden that the ETBE assessment "was nominated many years ago when it was considered a possible oxygenate . . . to replace" MTBE, another fuel oxygenator that is now the subject of ongoing litigation after the chemical contaminated drinking water in hundreds of jurisdictions around the country.

"But it is not" in use, Olden remarked. "I'll have to see why we're still looking at it." -- Maria Hegstad